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Complications of endovascular grafts in the treatment of pseudoaneurysms and stenoses in arteriovenous access

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Objective: **Endovascular stent grafts are utilized in the rescue of failing arteriovenous (AV) access. Reports claim the superiority of stent grafts and recommend these as a first-line treatment. We have observed a rise in the number of complications related to stent grafts in our patients. The following study was undertaken to assess the severity of these complications and their effect on access site maintenance.**

Methods: **We reviewed all patients who had endovascular stent grafts placed for treatment of failing dialysis access over the last 44 months. A series of 38 consecutively placed stent grafts was reviewed for stent migration, fracture, erosion, hemorrhage, and rupture at the site of the stent grafts. Hospital charts were reviewed to assess for indications, hemodynamic stability, transfusion requirement, and outcome.**

Results: **Of 38 stent grafts placed, nine were for pseudoaneurysm (PS), 20 for stenosis (ST), and nine for a combination (PS/ST). The average length of follow-up was 218.6 days. Primary patency was 49%, with an assisted primary patency of 76%. Eleven patients (28.9%) presented with complications related to migration, fracture, erosion, or rupture. Six were in the PS, three in the PS/ST, and two in the ST treatment groups. In all cases, migration or fracture of the stent graft led to recurrent pseudoaneurysm formation or erosion. Rupture occurred after a herald bleed in four cases. Once complication occurred, 10 of the 11 access sites had to be abandoned.**

Conclusions: **Significant life-threatening complication can arise when fracture and migration of the stent grafts used for treating AV access occur. Herald bleed with a previously placed stent graft may be a harbinger of future rupture. Complications appear less likely when stent grafts are used to treat stenosis; however, when complications occur, access site salvage is rare. Surgical revision in the case of pseudoaneurysm should be considered for access preservation. (J Vasc Surg 2013;57:144-8.)**

For many years, the gold standard of therapy for failing arteriovenous (AV) access has been angioplasty or surgical revision of stenotic lesions and surgical revision for pseudoaneurysmal AV fistulas. In many instances, surgical revision requires placement of temporary dialysis catheters while the revision heals. It is felt that catheter placement can cause undue risk to the patient, related to catheter infection and overall patient mortality; the Kidney Dialysis Outcomes Quality Initiative guidelines stress that catheter usage should be kept to a minimum in this patient population. Over the past decade, an increasing emphasis has been placed on catheter-free dialysis access.[1]

Maintaining catheter-free dialysis access has become an increasing challenge. For this reason, more centers are aggressively treating stenosis with recurrent angioplasty and, when this fails, stent grafts. Recent studies have proposed that placement of stent grafts within the access can maintain the access patency more effectively than simple angioplasty.[2,3] In addition, pseudoaneurysms that become symptomatic secondary to skin erosion and poor flow are now being primarily treated with stent grafts to preserve the access site and prevent the need for catheter access.[3] Immediate success of these procedures is often cited to be 100% with a 6-month primary patency of 29% to 88.2%.[2-7]

The fistula first initiative has resulted in an increasing number of natural fistulas with the resultant need for salvage when complex problems (eg, pseudoaneurysm, long segment stenosis) arise. Grafts that are successful over long periods of time are also prone to similar issues. The early success that stent grafts have experienced in these patients has led to an enthusiasm for early placement of these devices even prior to attempts at more conventional intervention. A fistula first/stent graft second approach to maintaining access without the use of catheters has been suggested.[8] Other authors have cautioned with regard to this aggressive approach, citing infection and other potential complications as well as cost issues as reasons for not adopting this approach.[4,9,10] Recently, we have identified a series of complications related to stent migration, fracture, erosion, and even life-threatening hemorrhage. We reviewed our recent data to determine the incidence of these complications, the outcomes of the complications, and their implications related to graft longevity.

METHODS

Our study was a retrospective review of the data collected on dialysis access patients undergoing intervention at Akron General Medical Center between November 2007

From the Akron General Medical Center.

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and June 2011. Approval was obtained from the Institutional Review Board for review of all dialysis access intervention over a 5-year time period. This group of patients is a subset of that overall review.

We reviewed all patients who had endovascular stent grafts placed for treatment of failing dialysis access over 44 months. A series of 38 consecutively placed stent grafts was reviewed for stent migration, fracture, erosion, hemorrhage, and rupture at the site of the stent grafts. Hospital charts and outpatient records were reviewed to assess for indication for stent graft placement, type of complication encountered, primary and primary assisted patency at 180 days, and operative outcomes. Acute presentation was reviewed to assess for hemodynamic stability at time of presentation, presence of significant bleeding episode, transfusion requirement, procedures performed, and outcomes. In addition, records from the area-wide dialysis access coordinator were reviewed to assess for interventions performed, patency determinations, and complications identified outside of our facility. The coordinator receives data collection forms from all centers performing interventions within a three-county area and creates a comprehensive access history for each patient.

Pseudoaneurysm was defined as a focal dilation of the access greater than two times the size of the remainder of the access. Stenosis was defined as >60% luminal stenosis of the AV access on fistulagram. All diagnoses were made by standard fistulagram. Decision for stent grafting was at the discretion of the operator; however, primary stent grafting was performed only in the case of pseudoaneurysm. Stent grafting was performed for stenosis only after three prior attempts at angioplasty had led to recurrent failure. Stent graft placement was performed utilizing criteria that required 15% oversizing to the landing zone and requiring 1 cm of normal landing zone for overlap. Contraindications to placement included presence of skin erosion, history of prior access infection, or crossing the elbow or axilla with the stent graft.

RESULTS

A total of 38 stent grafts were placed during the 44-month period. During this same time period, a total of 1364 interventions were performed on either failed or failing dialysis access. Of the 38 stent grafts, nine were placed for pseudoaneurysm, 20 for stenosis, and nine for a combination of pseudoaneurysm and stenosis. Seventeen of the stent grafts were placed into AV fistulas and another 21 into AV grafts. Six of the 38 stent grafts were placed in the forearm position, and 32 were placed in the upper arm; no stent graft was placed across the antecubital fossa or the axilla. All were placed within the body of the access, and none were placed centrally to the access site. Stent graft direct puncture was a potential in all cases, however was much more commonly performed when pseudoaneurysm or pseudoaneurysm and stenosis were the indication for stent graft placement. Stent grafts were chosen based on anatomic considerations. These included Flair endovascular stent grafts (Bard, Inc, Tempe, Ariz), Fluency endovascular stent grafts (Bard, Inc), Viabahn endoprostheses (W. L. Gore and Associates Inc, Flagstaff, Ariz), and Covered Wallstents (Boston Scientific, Natick, Mass); there was no difference in complication rate related to any particular stent graft.

Table. Presentation and outcomes of stent graft complications

Presentation and outcomes	*Number of patients*
Presented with significant bleeding episode	6
Required emergent/urgent operation	6
Attempted access site salvage	6
Herald bleed (at least 72 hours prior to presentation)	4
Significant hemodynamic instability (systolic blood pressure <90)	4
Required blood transfusion (>1 unit packed red blood cells)	3
Erosion without bleed	2
Cardiopulmonary arrest	1
Mortality	1

The average age of the patients was 64.2 years; the male-to-female ratio was 21:17. Associated comorbidities included hypertension (76.3%), diabetes mellitus (52.6%), and coronary artery disease (42.1%). The stent grafts were followed for an average length of 218.6 days (range, 12-500 days), and median follow-up was 212 days. During this follow-up time, 11 patients (28.9%) presented with complications related to the stent graft site (seven female; four male). The average time to development of these complications following stent graft placement was 151 days (range, 16-267 days). Of the 11 patients with complications, nine occurred in patients with autogenous AV fistulas (three erosion, four migration, two fracture). Six patients (15.7%) presented with significant bleeding, four of whom had presented with a herald bleed within 72 hours of the time of presentation. All of these patients had their stent grafts performed for either pseudoaneurysm or a combination of pseudoaneurysm and stenosis. Four of the patients with bleeding presented with hemodynamic instability and shock, with systolic blood pressures <90 mm Hg on presentation in the Emergency Department. Among this group of patients, three required transfusion of greater than one unit of packed red blood cells secondary to acute blood loss anemia. All six patients required emergency surgical treatment, and in all episodes, salvage of the access was attempted. Immediate salvage of the access site was successful in only two cases. There was one 30-day mortality in this group of patients due to readmission for congestive heart failure and sepsis (Table).

Five patients had complications diagnosed without prior rupture or hemorrhage. Two of these related to erosion, two to migration and recurrent pseudoaneurysm, and two to fracture and recurrent pseudoaneurysm (one of these patients presented in the skin erosion group with

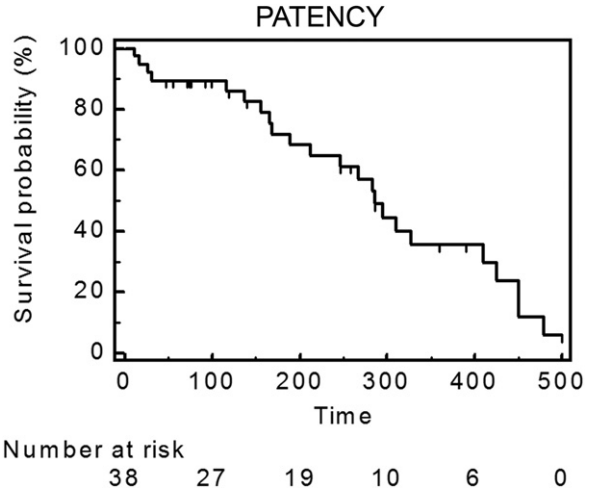

Fig 1. This Kaplan-Meier survival curve demonstrates the patency rate of fistulas post-stent graft placement followed out to 500 days.

fractured strut erosion). In each case, revision with access site salvage was attempted. Four patients had surgical revision while one had endovascular revision performed. All five initially were successful, but only the endovascular revision achieved long-term patency.

When reviewing the procedures, 92.7% (38 of 41) were technically successful initially. Primary patency for the 38 successful stent grafts was 47.4% at 180 days after stent graft placement. An assisted primary patency of 76.3% was noted in this group of patients. Kaplan-Meier plot for graft survival post-stent graft placement is included in Fig 1. Restenosis was the most common complication with stenosis at either end of the stent graft being the most prominent area of restenosis. Migration (four), fracture (four), and erosion (three) of stent grafts was noted in eleven patients. Complications were more prominent when the indication for placement of the stent graft was pseudoaneurysm or a combination of pseudoaneurysm and stenosis (9 of 18). Only two of the major complication noted occurred when the stent graft was placed for stenosis alone (2 of 20). This resulted in a relative risk ratio of 5 for complication when the indication for stent graft placement included pseudoaneurysm ($P < .01$; two-tailed Fisher exact test) When complications occurred, attempts to treat resulted in only one long-term success in preservation of the access site over the next 90 days.

DISCUSSION

The need for preservation of dialysis access without the use of temporary dialysis catheters is extremely important in decreasing both infection rates and mortality in the dialysis population.[1] Maintenance of existing dialysis access is of primary importance in this group of patients, and therefore many treatments have been devised to salvage failing and complicated dialysis access. Originally, surgical revision was felt to be the primary and only method obtaining any long-standing patency results. However, the advent of improved balloon angioplasty, stents, and, most recently, stent grafts has provided an attractive alternative to open surgical therapy.[2,3] The use of stent grafts has been recently advocated as the primary treatment for stenosis and pseudoaneurysm in AV access.[8]

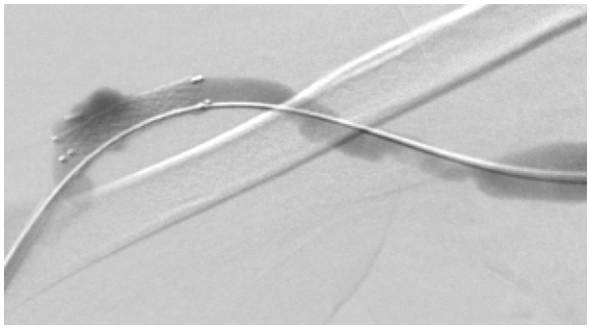

Fig 2. This image demonstrates migration of a stent graft back into a pseudoaneurysm sac. Both sac pressurization and complex tortuous anatomy were implicated in this case of migration.

The most common complications of stent grafts have been related to failure and restenosis. Various series have implicated stent grafts as having a higher risk of infection than angioplasty or bare metal stenting alone.[10,11] Our study reports a series of complications related to stent grafting that involve presentation of the patient with significant life-threatening bleeding, stent graft migration, stent graft fracture, and erosion. The complications encountered have various etiologies that may be mechanical or infectious in origin. Bleeding complications were related to episodes of migration, erosion, or fracture associated with their stent graft. Each of these complications can be considered separately as to their contribution to the ultimate outcome in these patients.

Migration of stent grafts appeared to be most prominent in those placed for pseudoaneurysm or a combination of pseudoaneurysm and stenosis. Reasons for this migration may be multifactorial. In some instances, it would appear that the pseudoaneurysms continued to be pressurized and continued to grow, which may have caused migration of the previously placed stent graft. In others, the tortuous anatomy associated with the pseudoaneurysm may have eventually caused the migration of the stent graft back into the aneurysm sac with subsequent arterial repressurization of the sac itself (Fig 2).

Migration may also occur secondary to fixation issues related to stent graft deployment. While there is no specific indication for use of stent grafts placed in this setting due to its off label indication, it is recommended that there be at least 1 centimeter purchase into “normal” AV fistula segments and at least 1 centimeter of overlap if more than one stent graft is placed.[12] Some stent grafts (Fluency) are uncovered at their proximal and distal attachment points for several millimeters, and even more attention to appropriate landing zones must be observed when these grafts are

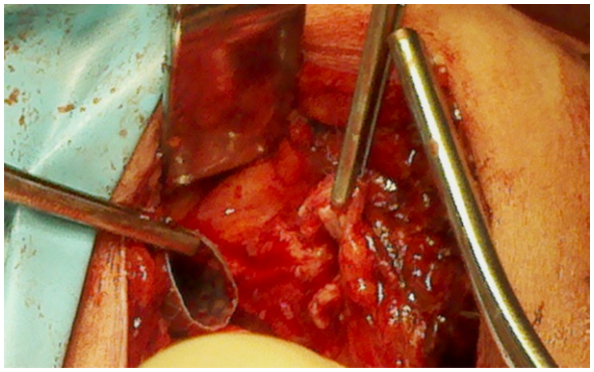

Fig 3. Lack of incorporation was identified in this stent graft that presented with rupture. The stent graft was easily removed from its distal landing site with gentle traction.

used. Finally, adequate oversizing of the stent graft may require at least a 15% diameter oversizing at the landing zones; however, optimal oversizing has yet to be determined in the setting of AV fistulas.[3] In addition, puncturing stent grafts that do not have adequate proximal and distal fixation zones may add to the potential for migration secondary to mechanical forces. Of note, is that when the stent grafts require removal during emergent operation, little fixation other than radial force is present and very little healing seems to be occurring in the setting of pseudoaneurysms (Fig 3). Early puncture in the face of poor incorporation may contribute to stent graft migration. For this reason, we have adopted a policy that stent grafts not be directly punctured for 4 to 6 weeks following placement.

This failure to incorporate may be multifactorial. Healing appears to be delayed at the stent graft/fistula interface. Ongoing inflammatory changes have been documented in prior studies, but most attention here has been paid to the effect this has on restenosis.[12] It is equally possible that these same changes create delayed initial incorporation and subsequent predilection for migration. This may be enhanced especially in the pseudoaneurysm population due to the potential low grade infection that these patients have exhibited in prior studies.[10,11] This combination of chronic inflammation and low grade infection may be a significant contributor to failure of incorporation, stent graft migration, and rupture.

Previous studies have discussed a higher prevalence of chronic infection in patients with pseudoaneurysm in whom stent grafts are placed.[10,11] There may be a threefold increase in these infections when compared with bare metal stents or angioplasty alone.[11] A combination of mechanical forces and chronic infection may be a further complicating issue when recurrent puncture of stent grafts is performed. In over half of the patients who presented with complications, recurrent punctures of the stent graft were being performed at the dialysis units. Several cases had notes from the dialysis units that documented difficulty in puncturing the access at the stent graft site, which resulted in multiple punctures being performed with each dialysis

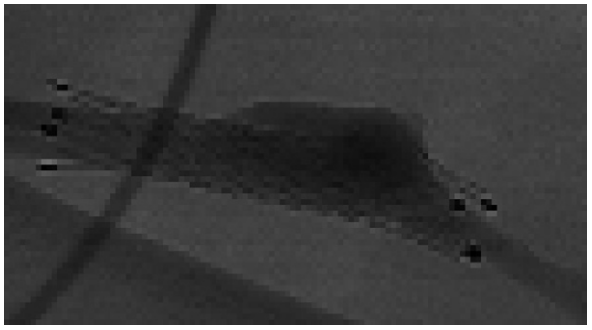

Fig 4. Stent fracture is seen at the base of this recurrent pseudoaneurysm. This occurred at the site of multiple previous punctures.

treatment. Finally, one patient had an attempt by their dialysis unit to reestablish a buttonhole at the site of the newly placed stent graft. This led to erosion and rupture, and we feel a buttonhole technique should never be used at the site of stent graft placement.

Another mechanism of failure is stent graft fracture (Fig 4). Each of these stent grafts had been punctured for ongoing dialysis multiple times, with strut fracture occurring at the puncture site. In our series, all stent grafts had the potential for being punctured during dialysis. In many cases, documentation from the dialysis centers notes difficulty in access at the sites of the stent grafts and often one or two particular sites were chosen due to ease of access. This may have led to increased risk of stent fracture and recurrent pseudoaneurysm in this group of patients. In one instance, an attempt to treat restenosis at the site of a prior stent graft placed for pseudoaneurysm caused fracture of the stent graft and led to repressurization of the aneurysm sac. Mechanical erosion of the fractured struts into the pseudoaneurysm wall may well have served as the lead point for recurrent pseudoaneurysm and potential rupture. In at least one case, a fractured strut of the stent graft was protruding through the skin at the time of surgery.

These complications are much more frequent in the group of patients who have pseudoaneurysm as an indication for stent graft placement. As previously noted, this association may be multifactorial and have both an infectious as well as a mechanical component. Surgical revision still remains a very good option for treatment of both stenosis and pseudoaneurysms in hemodialysis access. While surgical revision often requires placement of a temporary catheter while awaiting healing of the revision, long-term results are as good as the best in any of the stent graft series.[13-15] Many of the series touting stent grafts have only compared them with angioplasty alone and have not randomized patients into a surgical limb.[2,3,16] Other authors would point out that cost-effectiveness of stent grafting may not warrant its widespread use.[4,9] Our data suggests surgical revision should always be a consideration, especially when complex anatomy or potential pseudoaneurysm infection is considered. When possible, segments of graft/fistula that can still be accessed are left to avoid catheter placement.

It also appears that the subgroup of patients that develop complication related to migration, fracture, and rupture has a decreased long-term patency rate when compared with the group that experienced no such complications. Nine of our 11 patients required catheter placement as the complication resulted in failure of the access. Only one of our patients had >90 day patency observed. The complex nature of the access being treated initially may contribute to the failures seen once complications occur. Careful monitoring of the access once a stent graft is in place seems prudent. Early reintervention and surgical revision may salvage some of these access sites.

We have identified a subgroup of patients who present prior to rupture with a significant herald bleed. Each of these was characterized by an episode of protracted bleeding at the site of prior stent graft treatment post-dialysis treatment. While each of these stopped initially with conservative measures, recurrent bleeding and rupture occurred at the same site within 72 hours. This has caused us to adopt a policy that any patient with a stent graft in place and a significant prolonged bleeding episode post-dialysis be admitted for observation and have an urgent fistulagram performed. Failure to do so may result in rupture of the stent graft.

CONCLUSIONS

Stent grafts have been proposed as an alternative to catheter-free preservation of failing dialysis access. The current study documents the potential dangers that can occur with this therapy. Care must be taken to monitor both their use as well as any potential complications that occur secondary to the mechanisms described above. Evidence for migration, fracture, erosion, or infection requires aggressive therapy at the site of the previously placed stent graft. In particular, the presence of a significant bleeding episode in the area of a previously placed stent graft may be a harbinger of future serious and life-threatening bleeds.

Pseudoaneurysm, when treated with stent grafting, has significantly higher post-intervention complication rates than when stenosis is the indication. For this reason, primary surgical revision may still be the gold standard in the setting of pseudoaneurysm and complex anatomy; this is especially true if adequate sizing and landing zones for a stent graft cannot be assured. Finally, once complications of migration, fracture, erosion, and rupture occur, the chance of salvage of the AV access appears much less probable.

AUTHOR CONTRIBUTIONS

Conception and design: JZ, VE, DW
Analysis and interpretation: JZ, RN, VE, DW
Data collection: JZ, RN, DW
Writing the article: JZ, DW
Critical revision of the article: JZ, RN, VE, DW
Final approval of the article: DW
Statistical analysis: DW
Obtained funding: Not applicable
Overall responsibility: DW

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